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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WOODALL, NICHOLAS W	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

27

Office Action Summary	Application No. 10/773,581	Applicant(s) GINN, RICHARD S.	
	Examiner Nicholas Woodall	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-13 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-13 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 10/24/2007.

Allowable Subject Matter

2. The indicated allowability of claims 14 and 15 is withdrawn in view of the newly discovered reference(s) to Mikhail (U.S. Patent 5,308,349). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Wedeen (U.S. Patent 4,606,335).

Regarding claim 1, Kuslich discloses various embodiments of a device, for example Figure 28 showing a cerclage type embodiment, wherein the device comprises a band of biocompatible material having a height of at least that of a spinal disc to be treated and a first end and a length sufficient enough to wrap around the exterior of a spinal disc (see Figure 28). Regarding claim 3, Kuslich discloses a device wherein the first end of the band element includes an opening capable of receiving a hook.

Regarding claims 5 and 6, Kuslich discloses a device is capable of further comprising a heal-promoting material and an extra-cellular matrix material, such as hydroxyapatite,

on at least one side of the band. Regarding claims 7 and 8, Kuslich discloses a device that maybe comprised of a non-porous material or porous material depending on the intended use of the device. Regarding claim 10, Kuslich discloses a device comprising a second end that includes a connector capable of connecting the second end of the device to another portion of the device. Regarding claim 11, Kuslich discloses a device wherein the second end of the device is capable of being tied to another portion of the device and would require at least one thread extending from the second end of the device. Regarding claims 12 and 13, Kuslich discloses a device further capable of conducting electricity and having a power supply attached to the device to stimulate bone growth. Regarding claims 1 and 2, Kuslich fails to disclose further comprising an elongate member comprising a handle on the proximal end and a connector element on the distal end. Wedeen teaches a device comprising an elongated member comprising a handle on the proximal end and a connector element on the distal end, wherein the connector is a hook in order to position a cerclage device around a bone (column 1 lines 5-7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Kuslich with an elongated member comprising a handle on the proximal end and a connector element on the distal end in view of Wedeen in order to position a cerclage device around a bone.

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Wedeen (U.S. Patent 4,606,335) further in view of Mikhail (U.S. Patent 5,308,349).

Regarding claim 21, the combination of Kuslich and Wedeen disclose the invention as claimed except for the device further comprising a fork member. Mikhail teaches a device comprising a fork member comprising a proximal end and a distal end defining an axis therebetween (see Figures 8 and 9), wherein the distal end comprises a pair of tines comprising a transverse portion extending generally parallel to one another transversely with respect to the axis in order to distract adjacent bones of a joint. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the combination of Kuslich and Wedeen further comprising a forked member in view of Mikhail in order to distract adjacent bones of a joint.

Regarding claim 22, the combination of Kuslich, Wedeen, and Mikhail disclose a device wherein the transverse portions of each tine comprises a tip and a heel disposed proximal to the tip, a length between the tip and the heel wherein the tip is capable of engaging a first vertebra and pivotally engaging a second vertebra with the heel to adjust a distance between the vertebrae. Mikhail teaches a device for distracting joints as discussed above comprising the structure required by the claims that is fully capable of being used on a joint between two vertebrae of the spine.

6. Claims 1-8, 10-13, and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich (U.S. Publication 2002/0077701) in view of Kaladelfos (U.S. Patent 6,494,887).

Regarding claims 1, 23, and 27, Kuslich discloses various embodiments of a device, for example Figure 28 showing a cerclage type embodiment, wherein the device

comprises a band of biocompatible material having a height of at least that of a spinal disc to be treated and a first end and a length sufficient enough to wrap around the exterior of a spinal disc (see Figure 28). Regarding claim 3, Kuslich discloses a device wherein the first end of the band element includes an opening capable of receiving a hook. Regarding claims 5 and 6, Kuslich discloses a device is capable of further comprising a heal-promoting material and an extra-cellular matrix material, such as hydroxyapatite, on at least one side of the band. Regarding claims 7 and 8, Kuslich discloses a device that maybe comprised of a non-porous material or porous material depending on the intended use of the device. Regarding claim 10, Kuslich discloses a device comprising a second end that includes a connector capable of connecting the second end of the device to another portion of the device. Regarding claim 11, Kuslich discloses a device wherein the second end of the device is capable of being tied to another portion of the device and would require at least one thread extending from the second end of the device. Regarding claims 12 and 13, Kuslich discloses a device further capable of conducting electricity and having a power supply attached to the device to stimulate bone growth. Regarding claims 1, 2, 23, and 27, Kuslich fails to disclose the device further comprising an elongate member, wherein the elongate member includes a proximal end including a handle and a curved distal end including a connector, such as a hook, and a guide member, wherein the guide member includes a proximal end and a curved distal end having a radius of curvature substantially similar to an exterior perimeter of a spinal disc and a lumen extending between the proximal and distal ends capable of allowing at least a portion of an elongate element to pass.

Kaladelfos teaches a device comprising an elongate member (50), wherein the elongate member includes a proximal end including a handle and a curved distal end including a connector, such as a hook (54), and a guide member (12), wherein the guide member includes a proximal end including a handle and a curved distal end having a radius of curvature substantially similar to an exterior perimeter of a spinal disc and a lumen extending between the proximal and distal ends capable of allowing at least a portion of the elongate element to pass in order to insert an elongated element, such as a cerclage device, into a patient (column 1 lines 63-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Kuslich further comprising an elongate member and a guide member in view of Kaladelfos in order to insert an elongate element, such as a cerclage device, into a patient.

Regarding claim 24, the combination of Kuslich and Kaladelfos disclose a device wherein the lumen comprises a slot having a height greater than a width of the elongate element. Regarding claim 25, the combination of Kuslich and Kaladelfos disclose a device wherein the proximal end of the guide member defines an axis, wherein the distal end of the guide member terminates in a distal tip extending transversely with respect to the axis. Regarding claim 26, the combination of Kuslich and Kaladelfos disclose a device wherein the height of the lumen extends substantially perpendicular to the radius of curvature of the distal end.

Regarding claim 27, the combination of Kuslich and Kaladelfos disclose the invention as claimed except for the device further comprising a pair of guide members.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the combination of Kuslich and Kaladelfos including a pair of guide members, since it has been held that a mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

7. Applicant's arguments filed 10/24/2007 have been fully considered but they are not persuasive. The applicant's argument regarding claim 1 being a Jepson style claim making the preamble a structural limitation is not persuasive. A Jepson style claim is used to admit that the structure of the preamble of a claim is known prior art and that the novelty of the invention is an improvement described in the body of the claim. To reject a Jepson claim the examiner is then required to find the structure of the preamble as well as the improvement in use with the admitted prior art. The examiner would like to note that claim 1 does not have any structural elements in the preamble of the claim, therefore the examiner only needs to find the structural limitations in the body of the claim. Regarding the applicant's argument that Kuslich does not disclose a cerclage device capable of being wrapped around the outer diameter of an intervertebral disc space is not persuasive. The examiner would like to point the applicant to Figure 28 of the reference as discussed above, wherein Kuslich discloses an embodiment that is a cerclage device wrapped around the outer diameter of an intervertebral disc space. Regarding the applicant's argument that the Kuslich and Wedeen reference are not capable of being combined is not persuasive. The applicant agrees that Wedeen

teaches using an insertion device for deploying a wire, i.e. cerclage device, around the outside of a bone (page 7 lines 19-20). Kuslich discloses an embodiment comprising a cerclage device as discussed above. Therefore, the examiner believes the references are capable of being combined as discussed in the body of the office action. The applicant's argument that the Kuslich and Kaladelfos references can not be combined is not persuasive. Kaladelfos is being used by the examiner to teach a system for inserting a cerclage device, i.e. a wire/suture, comprising an elongate member and a guide member as discussed above in the body of the office action. Kuslich discloses an embodiment comprising a cerclage device as discussed above. Therefore, the examiner believes the references are capable of being combined as discussed in the body of the office action. The examiner has withdrawn previously indicated allowability of claims 14 and 15 making this office action non-final.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

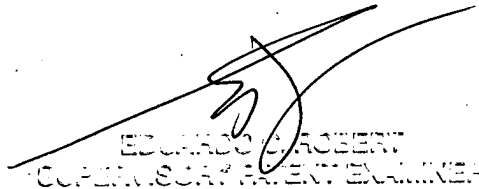
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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NWW



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